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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/727,151	12/02/2003	David K. Swanson	03-0515 (US01)	5305
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EXAMINER				
ROANE, AARON F				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/727,151

Applicant(s)

SWANSON, DAVID K.

Examiner

AARON ROANE

Art Unit

3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-20 and 28-43 is/are pending in the application.
- 4a) Of the above claim(s) 9,10,28-30,38 and 39 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 32-37,40 and 41 is/are allowed.
- 6) ☒ Claim(s) 1,3-8,11-20,31,42 and 43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 11-20, 31-37, 40 and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Gadsby et al. (USPN 5,309,909).

Regarding claim 1, Gadsby et al. disclose a carrier (12) movable between an unstressed state (figure 3) and a deflected and stressed state (figure 4); a tissue stimulation element (18, individually or collectively) supported by the carrier and capable of transmitting energy, wherein the carrier is configured to press the tissue stimulation element against tissue when in the deflected and stressed state; and a tissue engagement device (pointed tips of 18) carried by the carrier, configured to secure itself to tissue by piercing tissue and to secure the carrier to the tissue in the deflected and stressed state, see col. 3, line 53 through col. 6, line 29 and figures 1-4.

Regarding claims 3-5, Gadsby et al. further disclose the carrier includes a curved interior and first and second end portions, in the form of first and second tissue stimulation elements (the first end portion in the form of a tissue stimulation element is 18 located closest to 36 and the second end portion in the form of a tissue stimulation element is 18 located farthest from 36) and an interior portion and the carrier is configured such that the interior portion will be in spaced relation to the tissue when the end portions are in contact with the tissue and the carrier is in the unstressed state, see figures 1-4.

Regarding claims 6 and 7, Gadsby et al. disclose the claimed invention, see figures 3 and 4.

Regarding claims 11 and 12, Gadsby et al. disclose the claimed invention, see figures 3 and 4.

Regarding claims 19 and 20, Gadsby et al. further disclose a flexible carrier (16) that is non-linear when in a relaxed state, see figures 3 and 4.

Regarding claim 31, Gadsby et al. disclose the claimed invention, see col. 3, line 53 through col. 6, line 29 and figures 1-4. Gadsby et al. disclose that the body (14) is 1 mm in thickness, see col. 4, lines 7-11 and figures 3 and 4. It is therefore straightforward to deduce that there is a point along the length of (18) that has a diameter between 0.5mm and 1mm, since (18) is cone shaped and at the point it has zero diameter while at its base

(interface of 12 and 18) it has a diameter of a little greater than 1mm as may be seen from figures 3 and 4.

Regarding claim 42, Gadsby et al. disclose the claimed invention, see figures 3 and 4.

Claims 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Tetzlaff et al. (USPN 6,277,117).

Regarding claims 13-15, Tetzlaff et al. disclose a forceps apparatus comprising a tissue stimulation element (electrodes 110 and 120) supported by the carrier, a means for securing (20) the forceps apparatus to the tissue structure by engaging a single side of the tissue structure (outside of a vessel) and pressing the stimulation element against the single side of the tissue structure, see col. 3, line 32 through col. 7, line 37 and figures 1-7 in general and col. 3-4 and col. 7 in particular.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 8 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tetzlaff et al. (USPN 6,277,117) in view of Nezhat (USPN 6,162,220).

Regarding claims 1 and 42, Tetzlaff et al. disclose a forceps apparatus comprising a means for securing or carrier (22 and/or 24) movable between an unstressed state (open and non-engaged state) and a deflected and stressed state (closed and/or tissue clamping engaged state); a tissue stimulation element (electrodes 110 and 120) supported by the carrier and capable of transmitting energy, wherein the carrier is configured to press the tissue stimulation element against tissue when in the deflected and stressed state, see col. 3, line 32 through col. 7, line 37 and figures 1-7 in general and col. 3-4 and col. 7 in particular. Tetzlaff fails to disclose a tissue engagement device carried by the carrier, the tissue engagement device being configured to secure itself to tissue by piercing tissue and to secure the carrier to the tissue in the deflected and stressed state and wherein the tissue engagement device comprises a sharpened end for piercing tissue. Nezhat discloses electrosurgical forceps and teaches providing the jaw electrodes (274, 276, 278 and 280) with tissue engagement devices (penetrating elements 282, 284, 286 and 288) that have sharpened ends for piercing tissue in order to provide improved current focusing characteristics and lessened heating of adjacent tissues, see col. 2, lines 25-41, col. 7, lines 13-28 and figures 1-8. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Tetzlaff et al., as taught by Nezhat, to provide the electrodes (tissue stimulation elements) with

needle/teethlike penetrating elements in order to improve current focusing characteristics and lessen heating of adjacent tissues.

Regarding claim 8, Tetzlaff et al. disclose a forceps apparatus comprising a means for securing or carrier (22 and/or 24) movable between an unstressed state (open and non-engaged state) and a deflected and stressed state (closed and/or tissue clamping engaged state); a tissue stimulation element (electrodes 110 and 120) supported by the carrier and capable of transmitting energy, wherein the carrier is configured to press the tissue stimulation element against tissue when in the deflected and stressed state, see col. 3, line 32 through col. 7, line 37 and figures 1-7 in general and col. 3-4 and col. 7 in particular. Tetzlaff fails to disclose first and second tissue piercing members carried by the carrier and to secure the carrier to the tissue in the deflected and stressed state. Nezhat discloses electrosurgical forceps and teaches providing the jaw electrodes (274, 276, 278 and 280) with tissue engagement devices (penetrating elements 282, 284, 286 and 288) that have sharpened ends for piercing tissue in order to provide improved current focusing characteristics and lessened heating of adjacent tissues, see col. 2, lines 25-41, col. 7, lines 13-28 and figures 1-8. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Tetzlaff et al., as taught by Nezhat, to provide the electrodes (tissue stimulation elements) with needle/teethlike penetrating elements in order to improve current focusing characteristics and lessen heating of adjacent tissues.

Regarding claim 16, Tetzlaff et al. disclose a forceps apparatus comprising a tissue stimulation element (electrodes 110 and 120), an anchor (22 and/or 24), associated with the tissue stimulation element, the anchor being configured to secure the surgical apparatus to the tissue by pressing the stimulation element against the tissue when the anchor is in a deflected and stressed state, see col. 3, line 32 through col. 7, line 37 and figures 1-7 in general and col. 3-4 and col. 7 in particular. Tetzlaff et al. fail to disclose that the anchor secures the surgical apparatus to the tissue by piercing the tissue. Nezhat discloses electrosurgical forceps and teaches providing the jaw electrodes (274, 276, 278 and 280) with tissue engagement devices (penetrating elements 282, 284, 286 and 288) that have sharpened ends for piercing tissue in order to provide improved current focusing characteristics and lessened heating of adjacent tissues, see col. 2, lines 25-41, col. 7, lines 13-28 and figures 1-8. The combination provides a forceps device that secures to tissue via pressing and tissue piercing teeth. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Tetzlaff et al., as taught by Nezhat, to provide the electrodes (tissue stimulation elements) with needle/teethlike penetrating elements in order to improve current focusing characteristics and lessen heating of adjacent tissues.

Regarding claims 17 and 18, Tetzlaff et al. disclose the claimed invention.

Regarding claim 19, Tetzlaff et al. further disclose anchor includes a flexible carrier (proximal portion of 20 comprising 12, 14, 32 and 34), see col. 4, lines 35-67 and figures 1-8.

Regarding claim 20, Tetzlaff et al. disclose the claimed invention, see figure 3 where 12 and 14 are not aligned.

Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tetzlaff et al. (USPN 6,277,117) as applied to claim 13 above, and further in view of Nezhat (USPN 6,162,17220).

Regarding claim 43, Tetzlaff et al. disclose the disclosed invention except for reciting the means for securing the surgical apparatus to the tissue comprises a sharpened end for piercing tissue. Nezhat discloses electrosurgical forceps and teaches providing the jaw electrodes (274, 276, 278 and 280) with tissue engagement devices (penetrating elements 282, 284, 286 and 288) that have sharpened ends for piercing tissue in order to provide improved current focusing characteristics and lessened heating of adjacent tissues, see col. 2, lines 25-41, col. 7, lines 13-28 and figures 1-8. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Tetzlaff et al., as taught by Nezhat, to provide the forceps (means for securing) with needle/teethlike penetrating elements in order to improve current focusing characteristics and lessen heating of adjacent tissues.

Allowable Subject Matter

Claims 32-37, 40 and 41 are allowed.

Response to Arguments

Applicant's arguments with respect to claims 1, 3-8, 11-20, 31, 42 and 43 have been considered but are moot in view of the new ground(s) of rejection. Although there is a new grounds of rejection, the rejections are made with the same prior art of record as the last rejection, but are based on the new interpretation of the prior art of record which was necessitated by the amendments.

Regarding the rejections based on the Gadsby patent, due to the amendments it was necessary to interpret the tips of the pointed electrodes 18 as the tissue engagement device, which certainly secures itself to the tissue at least laterally.

Regarding the rejections based on the Tetzlaff et al. patent (or Tetzlaff et al. in view of Nezhat), Applicant's amendments to the independent claims necessitated the interpretation of 22 (and/or 24) as the carrier as opposed to (20) as in the previous office action.

This action is made FINAL.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON ROANE whose telephone number is (571)272-4771. The examiner can normally be reached on Monday-Thursday 7AM-6PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Aaron Roane/
Examiner, Art Unit 3739

/Henry M. Johnson, III/
Primary Examiner, Art Unit 3739